SB 8-75-S3

DEPARTMENT OF THE ARMY SUPPLY BULLETIN

Army Medical Department Supply Information

Headquarters, Department of the Army, Washington, DC 20310-2300 20 March 2006

Effective until rescinded or superseded

REPORTING ERRORS AND RECOMMENDING IMPROVEMENTS

You can improve this publication. If you find any mistakes, or you know a way to improve it, please let us know. Mail your letter or DA Form 2028 (Recommended Changes to Publications and Blank Forms) directly to the U. S. Army Medical Materiel Agency, ATTN: MCMR-MMO-S, Fort Detrick, MD 21702-5001. If you prefer using email, please address it to usammacrm@amedd.army.mil.

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SPECIAL NOTICE

THIS SUPPLY BULLETIN IS DEDICATED ENTIRELY TO
MEDICAL MATERIEL INSTRUCTIONS FROM THE
US ARMY MEDICAL MATERIEL AGENCY FOR THE DEPARTMENT OF DEFENSE

SECTION 1. MEDICAL MATERIEL INSTRUCTIONS

1-1. SUBMITTING MEDICAL/DENTAL PRODUCT QUALITY DEFICIENCY REPORTS (M/DPQDR) – [FORMERLY MEDICAL MATERIEL COMPLAINTS (SF 380'S)]

a. All medical materiel complaints, regardless of procurement source, should be submitted on a Medical or Dental Product Quality Deficiency Report (M/DPQDR). A M/DPQDR should be submitted to report materiel or equipment that has been determined to be harmful and/or defective that may result in death, injury, or illness. M/DPQDRs are categorized into two types:

• Category I: Materiel that has been determined by use or testing to be harmful or defective to the extent that its use has or may cause death, injury, or serious illness.

• Category II: Drugs, devices, supplies, or equipment that is suspected of being harmful, defective, deteriorated, or unsatisfactory because of malfunction or design, which are attributable to faulty materiel, workmanship and/or quality inspection, or performance or are otherwise unsuitable for use.

b. An M/DPQDR is the customer's way of alerting the system that there is a quality deficiency with a medical or dental product. Deficiencies should be submitted on standard and nonstandard items. It is also the vehicle for submitting Safe Medical Device (SMD) incidents. Examples of discrepancies which should be reported on the M/DPQDR are:

- Wrong or deficient labeling
- Foreign or particulate matter in liquids and solids
- Imperfectly manufactured items which are off-color, off-taste, and off-odor
- Suspected sub-potency or super-potency
- Defective devices
- Pinholes in tubing
- Faulty calibrations
- Systemic equipment failures
- Poor quality products

c. The submitter will receive a copy of the e-mail that has been sent to DSCP, the Defense Medical Standardization Board (DMSB) and the Services' Medical Logistic Offices at Ft Detrick. Once the form is received, DSCP will assign a Report Control Number (RCN) in the Product Data Reporting and Evaluation Program (PDREP), and respond back to you normally within two days. For more information about the PDREP program go to the following website:

http://www.nslcptsmh.navsea.navy.mil/pdrep/pdrep.htm

d. Report the circumstances of Category I (Type I complaints) immediately to DSCP, through the M/DPQDR, or by telephone.

(1) During normal duty hours (0700 - 1700 hours Eastern Time), call the DSCP Emergency Supply Operations Center (ESOC) at DSN 444-2111/2112, or commercial 215 737-2112. A telefax may also be sent to: Commercial 215 737-2081/7109 or DSN 444-2081/7109.

(2) After duty hours, the numbers called above will automatically transfer to the Staff Duty Officer. If the transfer does not occur or the call is not answered, call the following numbers: DSN 444-2341 or commercial 215 737-2341.

e. The 21 CFR prescribes reporting certain materiel/equipment conditions to the FDA under the Safe Medical Devices Act (SMDA). Logistics personnel will coordinate and provide a copy of the Complaint Form to the Risk Manager as part of the Risk Management Program. The Risk Manager is required under Joint Commission on Accreditation of Healthcare Organization (JCAHO) to review the SMDA information on the Complaint Form and assess the potential risk.

A sample of the M/DPQDR is shown at Appendix A.

1-2. DEPARTMENT OF DEFENSE MEDICAL MATERIEL QUALITY CONTROL (DOD-MMQC) MESSAGES AND DEPARTMENT OF THE ARMY MEDICAL MATERIEL INFORMATION (MMI) MESSAGES

a. The DoD-MMQC messages is a Tri-Service centralized reporting system developed to maintain a readiness posture by providing our MTOE activities, ships, and other deployed field units the same quality assurance (QA) information afforded fixed/TDA facilities. The DoD-MMQC process is an Integrated Medical Logistics Group initiative, designed to simultaneously disseminate QC information and rapidly notify hospitals, clinics, and medical units aboard ships or on foreign soil of potentially hazardous medical materiel. These messages contain urgent QA data emanating from pharmaceutical and/or medical device and equipment manufacturers regarding their products.

b. Once received at the Defense Supply Center Philadelphia (DSCP), research is conducted by DSCP and USAMMA's Distribution Operations Center (DOC) (MCMR-MMO-SO) to equate the product with National Stock Numbers (NSNs). USAMMA's DOC then incorporates information into the DoD-MMQC message format that contains all Service-specific requirements, Point of Contact (POC), reason for message, disposition instructions, and any other product related information. The program's primary purpose is to aid the Service-specific logisticians, supply managers, pharmacists, clinicians, medical maintenance personnel, in assuring that the proper use, handling, and return of recalled product is accomplished to protect patient safety.

c. The recalls are classified as follows:

(1) Class I: A situation in which there is a reasonable probability that use of, or exposure to, a dangerous product will cause serious adverse health consequences or death.

(2) Class II: A situation in which the use of, or exposure to, a dangerous product may cause adverse health consequences.

(3) Class III: A situation in which the use of, or exposure to, a dangerous product is not likely to cause adverse health consequences.

d. The DOC also disseminates Army Medical Materiel Information (MMI) messages that contain information specific to the Army only.

e. These messages are available via two media:

(1) The World Wide Web (WWW) (available on the USAMMA Homepage at http://www.usamma.army.mil. Select "DoD-MMQC Messages" and follow appropriate prompts.

(2) Electronic Mail. Register to receive DoD-MMQC and MMI messages via e-mail by subscribing on USAMMA's website (address above). Select "DoD-MMQC Messages" the "Subscribe to MMQC Messages Here" and provide all required information.

f. These messages are also disseminated via:

(1) File-transfer protocol (FTP) to USAMMCE (Germany) and 16th MLB (Korea)
(2) Joint Medical Asset Repository (JMAR)
(3) Defense Medical Logistics Supply System (DMLSS)

1-3. SAFE MEDICAL DEVICE ACT (SMDA) OF 1990

a. References:
(1) AR 40-61, Chapter 4, Section V, Para 4-13 and 4-14
(2) FDA Medical Device Report (MDR) Regulation (Website: www.fda.gov)
(3) Medical/Dental Product Quality Deficiency Report (M/DPQDR)

b. Effective 28 November 1991, all Medical Treatment Facilities (MTFs) are required to report device-related deaths, serious injuries and reportable malfunctions.

c. The M/DPQDR and the MedWatch 3500A Mandatory Reporting Form, will continue to be used in submitting the incidents, and is not limited to devices, and includes equipment as well as pharmaceuticals. All Activities should continue to submit M/DPQDRs, IAW AR 40-61, dated 28 Jan 2006, Chapter 4, Section V, Para 4-13 and 4-14.

d. M/DPQDR reports are not defined as Type I, Type II or Type II complaints [as previously identified with Medical Materiel Complaints (SF 380's)]. Categories of the M/DPQDR are categorized as a category 1 or 2. A category 1 complaint is described as an item or event that could cause serious injury or illness or loss of life. Category 1 can only be submitted with the approval of a medical officer. All others are category 2.

e. User-facilities such as hospitals and nursing homes are legally required to report suspected medical device-related deaths to both the Food and Drug Administration (FDA) and the manufacturer, if known, and serious injuries to the manufacturer or to FDA, if the manufacturer is unknown. These reports must be made on the MedWatch 3500A Mandatory Reporting Form.

f. The statutory authority for the MDR regulation is section 519(a) of the Federal Food Drug & Cosmetic (FFD&C) Act as amended by the SMDA of 1990. The SMDA requires user facilities to report:

(1) device-related deaths to the FDA and the device manufacturer;
(2) device-related serious injuries to the manufacturer, or to FDA if the manufacturer is not known; and
(3) submit to FDA on an annual basis a summary of all reports submitted during that period

g. The SMDA requires FDA to issue regulations requiring distributors to report device-related deaths, serious injuries and reportable malfunctions. In addition, the SMDA requires distributors and manufacturers to certify to FDA the number of MDR reports filed or that no reports have been filed. All manufacturers of finished medical devices and components which are ready for use, including foreign manufacturer's are now subject to the requirements of the MDR regulation, despite registration status.

1-4. SUBMITTING SUPPLY DISCREPANCY REPORTS (WebSDR) – [FORMERLY REPORTS OF DISCREPANCY (SF 364)]

a. All Supply Discrepancy Reports should be done electronically under the Department of Defense's Supply Discrepancy Reporting (SDR) system created by the Defense Logistics Agency (DLA). The Defense Automatic Addressing Service Center (DAASC) is responsible for the development and support of this project.

b. The goal of WebSDR is to move SDRs into an integrated transactional environment thereby providing an effective means to report and measure discrepancy related data and pipeline performance and to help achieve near real time SDR reporting, enable Perfect Order Fulfillment computations, facilitate interoperability internal and external to DoD, and maximize the economy, efficiency, effectiveness of the reporting process.

c. To submit a SDR on-line, go to: **https://www.daas.dla.mil/websdr**

d. You must register, providing all information required; once complete, submit and you will be provided a password. Once received, then comply with instructions outlined. For more information on this web site and the WebSDR Application, choose "Contact Us" (top right hand corner) on web page.

1-5. POINT OF CONTACT

Questions regarding the information contained within this SB may be directed to:

USAMMA
ATTN: MCMR-MMO-SO
1423 Sultan DR
Fort Detrick MD 21702-5001
DSN 343-4300/3242 or Commercial301-619-4300/3242

APPENDIX A. SAMPLE M/DPQDR

DMMonline
Directorate of Medical Materiel

The Warfighter's Medical Logistics Portal

Pharm | Med/Surg | Equipment | Readiness | Order Products | Customer Service | Site Log In

Medical/Dental Product Quality Deficiency Report

Complete the following data fields that are applicable to your Medical/Dental Product Quality Deficiency Report (M/DPQDR).
The M/DPQDR replaces the Standard Form 380 (SF380).
The submitter must provide an accurate email address and will automatically receive a copy of data submitted.
When finished, click on the Submit button at the bottom.
For further instructions about how this form should be completed, please click here.

Date deficiency found or event occurred ____ Assigned Document Number ____

Complaint Information

Category: ○ **I** Product or event that could cause serious injury or death

○ **II** All others

Cause of Complaint - Explanation of unsatisfactory condition, deficiency, or description of reaction

Approximate amount of time in use before failure(days) ____

Total patients involved ____ Total reactions ____ Patients without reaction ____

Note: Complete the following items for DoD category **I** complaints only

Reactions requiring hospitalization ____ Length of hospital stay (days) ____ Severe or unusual reactions ____

Product Information

NSN (if known) ____ Part or model number* ____ Serial number ____

***For pharmaceuticals, indicate either the NDC or UPC numbers**

Item description

Lot numbers (defective) ____ Batch number ____ Defective item is ____ Item under warranty ____

Quantity on-hand | Quantity recieved | Quantity inspected | Quantity deficient | Quantity suspended

Manufacturer name | Manufacturer phone | CAGE code (if known) | Manufacturer address

Vendor/Distributor name | Vendor/Distributor phone | CAGE code | Vendor/Distributor address

What is the current location of the defective materiel (provide DoDAAC if known)

Procurement Information

Contract Number | DoD Requisition Number* | Purchase Order Number

*** 14 digit code for refund on DFAS items**

Source of procurement | If other, please specify | Gov. furnished?

Date packed | Expiration date | Date recvd/repaired

Unit cost | Estimated repair cost

Actions

Has the manufacturer or distributor been notified? ☐ Yes ☐ No ☐ N/A

If so, which company was notified? What actions were taken?

Do you seek credit or replacement? ☐ Credit ☐ Replacement ☐ N/A

MedWatch Report

Was the MedWatch Report submitted to the FDA? (see instructions) ☐ Yes ☐ No ☐ N/A

If yes, was it?

☐ Mandatory 3500A Form http://www.fda.gov/medwatch/safety/3500a.pdf

☐ Voluntary 3500 Form https://www.accessdata.fda.gov/scripts/medwatch

☐ No form submitted

If no, do you want DSCP to submit a Voluntary MedWatch Report for you? We will provide you a copy of what is reported. ☐ Yes ☐ No ☐ N/A

From

Activity name	DoDAAC	Activity address

Submitter's name	DSN phone	Comm. phone	Fax	Email

Supply Officer's name	DSN phone	Comm. phone	Fax	Email

PoC for additional info	DSN phone	Comm. phone	Fax	Email

Authorizing Medical Officer for Category I complaints	DSN phone	Comm. phone	Fax	Email

Any other comments or questions relating to this complaint

Submit Query Start over

GLOSSARY

2006 GLOSSARY FOR SB 8-75-S3

Abbreviation/Acronym	Definition
AMEDD	Army Medical Department
CFR	Code of Federal Regulations
DA	Department of the Army
DAASC	Defense Automatic Addressing Service Center
DOC	Distribution Operations Center
DLA	Defense Logistics Agency
DMLSS	Defense Medical Logistics Supply System
DOD	Department of Defense
DOD-MMQC	Department Of Defense Medical Materiel Quality Control
DMSB	Defense Medical Standardization Board
DSCP	Defense Supply Center Philadelphia
DSN	Defense Switched Network
ESOC	Emergency Supply Operations Center
FDA	Food and Drug Administration
FFD&C	Federal Food Drug & Cosmetic
FTP	File Transfer Protocol
JCAHO	Joint Commission on Accreditation of Healthcare Organization
JMAR	Joint Medical Asset Repository
MMI	Medical Materiel Information
MMQC	Medical Materiel Quality Control
M/DPQDR	Medical or Dental Product Quality Deficiency Report
NSN	National Stock Number
PDREP	Product Data Reporting and Evaluation Program
POC	Point of Contact
PQDR	Product Quality Deficiency Report
QDR	Quality Deficiency Report
RCN	Report Control Number
SF	Standard Form
SDR	Supply Discrepancy Reporting
SMD	Safe Medical Device
SMDA	Safe Medical Devices Act
USAMMA	United States Army Medical Materiel Agency
USAMMCE	United States Army Medical Materiel Center, Europe
USAMRMC	United States Army Medical Research and Materiel Command

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By Order of the Secretary of the Army:

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General, United States Army
Chief of Staff

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Secretary of the Army

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